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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,510	10/27/2003	Eugene M. Breznock		2672

7590 08/15/2006

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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,510	BREZNOCK ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15, 21-23, 25, 27 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15, 21-23, 25, 27, 29-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, filed June 12, 2006, with respect to the rejection(s) of claim(s) 9-15, 21-26 and 31 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruce (U.S. Patent No. 5,800,409).

With respect to **Claim 9**: With respect to the step of inserting a tapered tip of a flexible trocar, Bruce teaches inserting flexible trocar 54 having tapered tip 58 into the distal end of axially elongate tube 10 into an incision into the suprapatellar pouch of a human knee. This device is also considered herein to be capable of being inserted into an incision into the thoracic cavity of a mammalian patient. Trocar 54 is inserted through a drainage lumen 38 of bidirectional, nonremovable valve 44 attached to a proximal end of tube 10 and through drainage lumen 39 and extends substantially the length of the axially elongate tube. With respect to the step of

Art Unit: 3761

selectively bending a region near the distal tip of the axially elongate tube, upon removal of trocar 54 from tube 10, Bruce teaches applying force to the proximal end of the tube as a natural process of inserting said tube 10, resulting in the bending of tip 14 of tube 10. The force drives the bending and therefore the bending of tip 14 steers the tube 10 into the suprapatellar pouch or thoracic cavity. With respect to the step of selectively opening or closing a valve, valve 44 has "on" and "off" positions to allow selective opening and closing to control the efflux and influx of fluid, air or contaminants into the thoracic cavity through drainage lumen 39 of tube 10.

With respect to **Claim 10**: Bruce teaches filling the cavity wherein the tube 10 is introduced with saline to afford a clear view at the proximal end, where bending is controlled and tortuous anatomy can be navigated.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13, 21-23, 25, 31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce (U.S. Patent No. 5,800,409).

With respect to **Claim 13**: Bruce teaches advancing tube 10 comprising flexible trocar 54 having tapered tip 58 and a guidewire lumen extending the length of said trocar 54 into the pouch and subsequently removing trocar 54. Bruce does not teach a guidewire or a hollow needle, however both are well known in the art as being used in tandem with one another as an introducer device to place a delivery catheter such as that taught by Bruce, wherein both the needle and guidewire are removed once the catheter has been successfully placed, the

Art Unit: 3761

guidewire being removed last. With respect to the advancing step taught by Bruce, therefore, the guidewire lumen defined by the inner wall of trocar 54 would extend over the guidewire and through the hollow needle.

With respect to **Claims 21,34**: With respect to the step of inserting a tapered tip of a flexible trocar, Bruce teaches inserting flexible trocar 54 having tapered tip 58 into the distal end of axially elongate tube 10 into an incision into the suprapatellar pouch of a human knee. This device is also considered herein to be capable of being inserted into an incision into the thoracic cavity of a mammalian patient. Trocar 54 is inserted through a drainage lumen 38 of bidirectional, nonremovable valve 44 attached to a proximal end of tube 10 and through drainage lumen 39 and extends substantially the length of the axially elongate tube. With respect to the step of selectively opening or closing a valve, valve 44 has "on" and "off" positions to allow selective opening and closing to control the efflux and influx of fluid, air or contaminants into the thoracic cavity through drainage lumen 39 of tube 10. Bruce teaches advancing tube 10 comprising flexible trocar 54 having tapered tip 58 and a guidewire lumen extending the length of said trocar 54 into the pouch and subsequently removing trocar 54. Bruce does not teach a guidewire or a hollow needle, however the uses of both are well known in the art as being used in tandem with one another as an introducer device to place a delivery catheter such as that taught by Bruce, wherein both the needle and guidewire are removed once the catheter has been successfully placed, the guidewire being removed last. With respect to the advancing step taught by Bruce, therefore, the guidewire lumen defined by the inner wall of trocar 54 would extend over the guidewire and through the hollow needle.

With respect to **Claim 22**: With respect to the step of selectively bending a region near the distal tip of the axially elongate tube, upon removal of trocar 54 from tube 10, Bruce teaches applying force to the proximal end of the tube as a natural process of inserting said tube 10, resulting in the bending of tip 14 of tube 10. The force drives the bending and therefore the bending of tip 14 steers the tube 10 into the suprapatellar pouch or thoracic cavity.

With respect to **Claim 23**: Bruce teaches apertures 34 (sideports) located at the distal end of tube 10 operatively connected to drainage lumen 39.

With respect to **Claim 25**: Bruce teaches that the tip 14, valve housing 26 and attachment means 30 are injection molded to form a single piece instrument therefore the valve 44 is preattached to the tube 10 near the proximal end prior to removal of the instrument from its packaging.

With respect to **Claim 31**: Bruce teaches that attachment 30 allows the connection of a suction source and defines lumen 38 (valve-enabling lumen). Bruce teaches that the valve is rotated but does not explicitly teach how rotation is accomplished. Applying a suction flow is considered herein to be a viable method for rotating the valve to an "on", or open, position and it would be obvious to one of ordinary skill in the art to employ this method of opening the valve in the event that manual opening is neither possible nor practical, as is the case during a surgery.

With respect to **Claim 33**: Valve 44 would necessarily be normally closed as the valve is opened to allow fluid to enter or exit tube 10, thus when not in use, the valve would be closed.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce ('409) in view of Kortelling (U.S. Patent Application Publication No. 2002/0161353).

With respect to **Claim 11**: Bruce does not teach that retraction of tube 10 is caused by a control rod. Kortelling teaches a steerable catheter having control rods 54 disposed on opposing ends of a diameter D of the tip of the catheter wherein longitudinal pulling or movement of either of the rods results in deflection of the tip across said diameter. Kortelling teaches that the control rods steer the catheter while preventing movement away from the plane defined by the diameter D, preventing movement in an undesired direction, therefore it would be obvious to one of ordinary skill in the art to provide control rods to bend the tip of the device taught by Bruce as taught by Kortelling. ('353, ¶ 0047)

With respect to **Claim 14**: Bruce teaches that one end of trocar 54 is screwed to attachment means 30, therefore tube 10 is pre-mounted to trocar 54.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nissenbaum et al (U.S. Patent No. 6,669,708).

With respect to **Claim 12**: Bruce does not teach that bending of tip 14 is accomplished by shape-memory actuators. Nissenbaum teaches a flexible introducer device comprising a flexible tube, wherein bending of the tube is performed by electrically actuating shape memory alloy materials (shape memory actuator) formed as part of the introducer device. This electrical actuation can be targeted, wherein one actuator is enabled simultaneously with the opposing actuators not being activated. These materials are actuated by application of current (electrical

Art Unit: 3761

activation) to permit bending of the flexible tube portion. Nissenbaum teaches that the use of these materials to create flexible products is known in the art ('708, Col. 22, lines 9-23), and the method of electrical activation to allow bending taught by Nissenbaum constitutes an alternate method to the method of bending taught by Bruce, therefore it would be obvious to one of ordinary skill in the art to provide actuators comprised of shape memory materials that are activated electrically and selectively to permit a controlled degree and direction of bending.

Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce ('409) in view of Moy (U.S. Patent No. 5,509,909).

With respect to **Claims 15,27**: Bruce does not teach that the tube is subsequently fixed in position relative to the incision in the knee. Moy teaches clamp assembly 44 that fixes catheter 12 in place once the catheter is finally positioned. By fixing the catheter in place, suction can be applied with assurance that the bent secured catheter will not be inadvertently removed or displaced, therefore it would be obvious to one of ordinary skill in the art to secure the tube 10 taught by Bruce in position with a clamp as taught by Moy.

Claims 29, 30, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce ('409) in view of Conway et al (U.S. Patent No. 5,370,899).

With respect to **Claims 29,30,35,36**: Bruce does not teach activating an intracorporeal fixation device. Conway teaches a bendable catheter having a expandable sleeve to anchor the catheter in place that is attached to the catheter (i.e. an intracorporeal fixation device). Balloon catheters are well-known in the art as a drainage device that secures itself within a passageway

Art Unit: 3761

and does not need ongoing adjustment or reintroduction, therefore it would be obvious to one of ordinary skill in the art to provide a balloon structure to the device taught by Bruce as an intracorporeal fixation device to allow securement in place in a body cavity so as to eliminate the need for readjustment and possible contamination of the device.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over de la Torre et al (U.S. Patent No. 6,319,246).

With respect to **Claim 32**: Bruce does not teach rotating the valve to an "off" position by removing the vacuum from within valve-enabling lumen 38 and allowing an open-celled foam to close the valve. De la Torre teaches a laparoscopic device access port wherein the device has a valve that comprises an open celled foam that expands to close the valve. De la Torre teaches that other valve structures may also be employed. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency, *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

